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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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04/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/646,108

Applicant(s)

ROSENBERG, MEIR

Examiner

HELEN NGUYEN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-15 and 17-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-15, and 17-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 1/2/2008. Claims 1, 22, and 29 are amended. Claims 6 and 16 are cancelled, rendering the previous claim objections moot.

Claims 1, 3, 4, 7-15, and 17-33 pending and under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 29-33** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the recitation in Claim 29 of the second lumen being permanently sealed does not appear to be disclosed in the specification. Applicant's only appears to discuss that said second lumen is a fluid-filled sealed lumen. Moreover, does the recitation of permanently sealed mean that said device is a disposable one-time use device because the components cannot be taken apart? Or does it mean that said lumen does not allow the addition or release of any fluid into the lumen? In the rejection that follows, the Examiner has taken permanently sealed to mean closed without allowing fluid to enter or leave the lumen.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claim 1, 3-4, 8-10, 15, 17-18, 21-24, 28-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (US Pat No. 5951497) in view of Goodin et al (US Pat No. 4928693).

6. In regard to **Claims 1, 22, and 29**, Wallace et al disclose a pressure sensor device best seen in Figure 16, comprising: an elongate catheter 310 including a plurality of fluid-entry ports 332a formed in a sidewall thereof and having a first lumen 332 adapted to accommodate fluid flow therethrough and in fluid communication with the plurality of fluid-entry ports formed in the elongate catheter; a second, separate, fluid-filled, fluid-impermeable, permanently sealed lumen 330 extending between a distal flexible membrane 342 that is disposed extending across an opening formed in the sidewall of the catheter and is adapted to be exposed to an external pressure source (Col.17: 27-42), and a proximal pressure sensor 102 that is effective to measure pressure of the external pressure source in response to displacement of the pressure-sensitive component (Col.13: 48-60) when disposed flush across the opening, best seen in Figure 5-6, wherein Wallace et al also disclose using said pressure sensor device having many application of uses such as intra-ventricularly and thus must be implanted within a patient's ventricle for direct pressure readings (Col.17: 10-17).

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7. However, Wallace et al do not disclose said second lumen filled with an incompressible fluid. Goodin et al disclose an analogous pressure sensor device comprising a first 18 and second lumen 20, said second lumen filled with an incompressible fluid to enable effective transmission of pressure for accurate readings (Col.4: 19-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wallace et al such that said second lumen is filled with an incompressible fluid as taught by Goodin et al as an equally as effective means to transmit the pressure and thus provide accurate pressure readings.

8. In regard to **Claims 3 and 23**, Wallace et al disclose the flexible membrane 342 is disposed at a distal end of the second lumen 330, best seen in Figure 16, and the pressure sensor 102 is coupled to a proximal end of the second lumen, best seen in Figure 5-6.

9. In regards to **Claim 4**, Wallace et al disclose the flexible membrane 342 includes a first surface in contact with fluid within the second lumen, and a second, opposed surface adapted to be exposed to an external pressure source, best seen in Figure 16.

10. In regard to **Claims 24 and 30**, Wallace et al disclose the opening is formed in the sidewall of the catheter, best seen in Figure 16.

11. In regards to **Claim 9**, Wallace et al disclose the second lumen 330 contains a predetermined volume of fluid.

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12. In regards to **Claim 10**, Wallace et al disclose the second lumen 330 is free of voids.
13. In regards to **Claim 15**, Wallace et al disclose the second lumen has a diameter that is less than a diameter of the first lumen (Col.4: 20-24).
14. In regards to **Claim 17**, Wallace et al disclose the catheter 310 has a compliance (Col.9: 2-5) that is less than a compliance of the flexible membrane 342 (Col.9: 55-62; Col.10: 16-31).
15. In regards to **Claim 18**, Wallace et al disclose the catheter 310 has a low compliance such that it is not susceptible to deformation as a result of exposure to the external pressure source (Col.9: 2-5).
16. In regard to **Claims 21 and 28**, Wallace et al disclose the flexible membrane 342 comprises a flexible sleeve that is formed around a distal end of the catheter and that is in fluid communication with the second lumen 330, best seen in Figure 16.
17. In regards to **Claim 8**, Wallace et al in combination with Goodin et al disclose the invention above but do not disclose the flexible membrane 342 formed of a material selected from the group consisting of polyurethane, silicone, and solvent-based polymer solutions. However, Wallace et al disclose do disclose that said flexible membrane is made of an elastomer (Col.9: 59-62) and that one example of an elastomer is polyurethane (Col.8: 65-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

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to make the flexible membrane of Wallace et al as modified by Goodin et al out of an elastomer such as polyurethane as taught by Wallace et al as an effective material for transmitting the pressure readings.

18. **Claims 7, 25, and 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al and Goodin et al, further in view of Goldstein et al (US Pat No. 5899937).

19. Wallace et al in combination with Goodin et al disclose the flexible membrane 342 above but do not specify its compliance. Goldstein et al teaches a pulsatile flow system with a device comprising a membrane with adjustable compliance capable of duplicating a compliance value of $0.008 \text{ cm}^3/\text{mmHg}$, which is the equivalent of $8\mu\text{L}/\text{mmHg}$ (column 10, lines 25-38), instead of a flexible membrane with a compliance in the range of $0.05\mu\text{L}/\text{mmHg}$ to $2\mu\text{L}/\text{mmHg}$ as disclosed by the applicant. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a flexible membrane with a compliance of $8\mu\text{L}/\text{mmHg}$ because Applicant has not disclosed that a membrane with a compliance in the range of $0.05\mu\text{L}/\text{mmHg}$ to $2\mu\text{L}/\text{mmHg}$ provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Goldstein et al.'s membrane and the Applicant's invention, to perform equally well with either the compliance as taught by Goldstein or the claimed membrane compliance of $0.05\mu\text{L}/\text{mmHg}$ to $2\mu\text{L}/\text{mmHg}$ because both would perform the same function of causing a shift in equilibrium, with little force, and transferring the pressure signal to the sensor.

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20. **Claim 14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al and Goodin et al, further in view of Sgourakes (US Pat No. 4638656).

21. Wallace et al in combination with Goodin et al disclose the fluid in the second lumen 330 above but do not disclose its kinematic viscosity. Sgourakes teaches a differential pressure transmitter 20 comprising a first and second lumen, 22 and 24, fluid-filled region 50, and flexible membranes 42 and 44. The viscosity of the fill-liquid in the fluid filled region 50 is 5 cs (column 4, lines 40-45) for the purpose of pressure detection. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Wallace et al as modified by Goodin et al such that the fluid in the second lumen has a viscosity of 5 cs as taught by Sgourakes to provide a fluid that accurately detects pressure.

22. **Claims 11, 13, 19, 26-27, and 32-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al and Goodin et al, further in view of Brockway et al (US Pat No. 4846191).

23. In regards to **Claim 11**, Wallace et al in combination with Goodin et al disclose the second lumen 330 above but do not disclose the volume of fluid in said lumen or the dimensions of diameter or length. Brockway et al disclose an analogous pressure sensor device comprising a lumen having a diameter in the range of about 0.1 mm to 0.3 mm and a length in the range of about 5 cm to 20 cm (Col.6: 13-16). From these dimensions, Brockway et al teach that the lumen is capable of holding 3 μ L of fluid, which in the range of about 1 μ L to 10 μ L. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

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to make the diameter and length of the second lumen of Wallace et al as modified by Goodin et al in the range of about 0.1 mm to 0.3 mm and 5 cm to 20 cm respectively, such that the volume of fluid contained is in the range of about 1 μL to 10 μL as taught by Brockway et al, as effective dimensions for the desired use.

24. In regard to **Claims 13, 26, and 32**, Wallace et al in combination with Goodin et al disclose the fluid in the second lumen 330 above but do not disclose said fluid as biocompatible and with a low viscosity. It is noted that Goodin et al teach the fluid is saline which is known to possess low viscosity (Col.4: 19-24). Brockway et al disclose an analogous pressure sensor device comprising a lumen 28 filled with a biocompatible low viscosity fluid 29 to effectively obtain pressure readings (Col.5: 24-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the fluid in the second lumen of Wallace et al as modified by Goodin et al to be biocompatible and have a low viscosity as an effective means to transmit the pressure for accurate readings and prevent harmful reactivity with the body in case of leakage respectively.

25. In regard to **Claims 19, 27, and 33**, Wallace et al in combination with Goodin et al disclose the pressure sensor 102 above but do not disclose the sensor having a frequency response that is greater than 20 Hz. Brockway et al disclose an analogous pressure sensor device with a pressure sensor having a frequency response at greater than 20 Hz (Col.6: 30-37) as an effective response frequency for measuring pressure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pressure sensor of

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Wallace et al as modified by Goodin et al have a frequency response that is greater than 20 Hz as taught by Brockway et al as an effective response frequency for measuring pressure.

26. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al and Goodin et al, further in view of Cosman (US Pat No. 4385636).

27. Wallace et al in combination with Goodin et al disclose the second lumen 330 with fluid above, wherein Goodin et al disclose the fluid is saline which is known to possess low viscosity (Col.4: 19-24, but do not disclose the fluid is silicone fluid. Cosman teaches that silicone fluid is effectively used to transmit pressure (Col.14: 18-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the low viscosity fluid of Wallace et al as modified by Goodin et al to be a silicone fluid as taught by Cosman as an effective fluid to transmit pressure for accurate readings.

28. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al and Goodin et al, further in view of Mann et al (US Pat No. 20040167580).

29. Wallace et al in combination with Goodin et al disclose the pressure sensor 102 above but do not disclose the range of compliance of said sensor. Mann et al teach that a pressure sensor with a low compliance is desirable to prevent errors in sensed pressure readings (§0156) but do not explicitly state a value for said compliance. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the pressure sensor with a compliance in the range of about 0.1µL/mmHg to 0.02µL/mmHg because Applicant has not disclosed that a pressure sensor with such a specific compliance

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provides an advantage, is used for a particular purpose, or solves a stated problem, other than that a low compliance is desirable just as Mann et al teach. One of ordinary skill in the art, furthermore, would have expected the pressure sensor of Mann et al and the Applicant's invention, to perform equally well in the function of pressure sensing as both disclose measuring pressure with a sensor of low compliance. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pressure sensor of Wallace et al as modified by Goodin et al to have a low compliance as taught by Mann et al, such as the range of 0.1 $\mu\text{L}/\text{mmHg}$ to 0.02 $\mu\text{L}/\text{mmHg}$.

Response to Arguments

30. Applicant's arguments filed 1/2/2008 have been fully considered but they are not persuasive. Applicant contends that Wallace et al teach away from using incompressible fluid (liquid) in the second lumen, citing portions of Wallace et al addressing the issue of having fluid present in the air column. However, it is noted that fluid in the form of condensation is only undesirable when using an air column because the presence of the fluid can alter the pressure measurements. Thus, if the rejection above involved using a second lumen containing both air and liquid, it would be correct to say that Wallace et al teach away from such modification. However, in the instant case, one mechanism of sensing pressure is simply being replaced with another, i.e. using a liquid-filled lumen instead of an air-filled lumen. Therefore, it is maintained that Wallace et al do not teach away from such modification. Rather, because the use of an incompressible fluid for pressure sensing was well known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art to substitute the air-filled

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lumen with a liquid-filled lumen because the substitution would have yielded predictable results and still allow the device to effectively sense pressure.

31. Furthermore, Applicant is reminded that for a proper §103 rejection, "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In *re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). "There is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (*Ruiz* at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (*National Steel Car v. Canadian Pacific Railway Ltd.*, 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004))." See MPEP 2143.01. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969.

32. In regard to Claim 22, Applicant contends that Wallace et al do not teach the membrane flush across an opening in the catheter. However, it is noted that the broadest reasonable definition of flush is "being right next to, immediately adjacent" (www.dictionary.com). Thus, according to said definition, Wallace et al do indeed teach the membrane 342 extending across an opening formed in the sidewall of the catheter and is adapted to respond to intra-ventricular pressure changes when disposed flush across the opening, wherein flush is defined as

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immediately adjacent, i.e. the membrane is immediately adjacent the opening, regardless of whether or not the membrane is filled with fluid, as best seen in Figure 16. Furthermore, it is noted that said recitation of the membrane "adapted to respond to intra-ventricular pressure changes when disposed flush across the opening" constitutes intended use, and that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is also noted that Wallace et al do indeed disclose the membrane extending across the opening as shown in Figure 16, wherein at least a portion of the membrane extends across the opening as claimed.

33. Moreover, it is also noted that while the drawings appear to show the membrane flush across the opening in the catheter, the specification provides no such disclosure. In fact, due to the fact that the catheter is filled with incompressible fluid, it is questionable as to how "flush" the membrane may be across the opening, given that the presence of the fluid within the lumen would necessarily bow the membrane outwardly to at least some extent.

34. In regard to Claim 29, Applicant contends that Wallace et al do not disclose the second lumen is permanently sealed. However, it is noted that although Wallace et al discloses charging the lumen to inflate the balloon by inserting male connector 72 of the catheter into female connector 98 of the attached pressure sensor 102, after such attachment there is formed an air tight column of fluid for measuring pressure. In fact, Wallace et al also disclose a locking device 134 used to retain the male connector in exact position within the female connector (see col.12-13). As such, it is maintained that Wallace et al teach the second lumen permanently sealed, at

least during at a point in time during use and before recharging, wherein said permanently sealed lumen corresponds to the locked air tight lumen of fluid that is used to transfer pressure.

Conclusion

35. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736